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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,725	09/18/2003	Manabu Nakatani	1/1395US	4358

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,725	NAKATANI ET AL.	
	Examiner	Art Unit	
	Caralynne Helm	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-15* is/are rejected.

7)☒ Claim(s) *1,14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3 pages*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2007 has been entered.

Applicant's arguments with respect to claims 1-3 and 6-15 have been considered but are moot in view of the new ground(s) of rejection. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Objections

Claims 1, 14, and 15 objected to because of the following informalities: the term "polyaxamers" appears to be a misspelling of poloxamers. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 6-15 are rejected under 35 U.S.C. 103(a) as being obvious over Friedl et al. (US 2005/0089575) in light of Gendron et al. (US2002/0137678), Parikh (Handbook of Pharmaceutical Granulation Technology), and the EPA Profile of the Pharmaceutical Manufacturing Industry.

Friedl et al. teach a pharmaceutical composition tablet comprising telmisartan and a diuretic (see title), where the telmisartan is present in a dissolving layer and the diuretic is present in a disintegrating layer (see paragraph 15). More specifically, Friedl et al. teach the composition as providing a dosage unit of 10-160 mg of telmisartan and comprising 3-50 wt% telmisartan (see paragraph 49), a basic agent at 0.25-20 wt% such as alkali metal hydroxides like NaOH and KOH, as well as basic amino acids, and meglumine (see paragraph 46), where the molar ratio of telmisartan to basic agent is exemplified at nearly 2 to 1 (see example 4), water soluble diluent at 60-80 wt% such as carbohydrates like glucose, oligosaccharides like sucrose, and sugar alcohols like sorbitol (see paragraph 47 and 49), Pluronic®, a trade name for a set of poloxamers, at 0-10 wt% (see paragraphs 55, 58, and 63), and from 0-30% of other additional lubricants, binders, flow control agents, crystallization retarders, solubilizers and color agents (see paragraphs 51-58). Friedl et al. thereby teach the limitations of instant claims 1-3, and 6-13, but do not specifically teach the Pluronic® (poloxamer) having an average molecular weight of 2000-12000. Gendron et al. teach that Pluronic® varieties, such as F68 and P103 with average molecular weights of 8400 and 4950 respectively, can be used to improve the

solubility of poorly water-soluble pharmaceutical compounds (see paragraph 72). Thus one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the teaching of Gendron et al. with the teaching of Friedl et al. to include a Pluronic® F68 or P103 to help solubilize the poorly water soluble telmisartan. Therefore, claims 1-3 and 6-13 are obvious over Friedl et al. in light of Gendron et al.

In addition, Friedl et al. teach multiple methodologies for the production of telmisartan material used to make tablets. One embodiment involves the spray drying of an aqueous solution containing telmisartan at 3-50 wt%, basic agents at 0.25-20 wt% and Pluronic® at 1-10 wt% (see paragraphs 55, 49, 63 line 11, 84, and 85 line 1). The granulate from the spray drying process is mixed with water soluble diluent at 30-95 wt% along with a lubricant at 0.1-5 wt% (see paragraphs 91-93). The resulting mixture can also contain other excipients and adjuvants (see paragraphs 51-58). Although not specifically disclosed by Friedl et al., Parikh teaches that ethanol is also a commonly used solvent in spray drying techniques (see page 92 paragraph 1 line 3); thus one of ordinary skill in the art at the time the invention was made would have found it obvious to employ ethanol as an additional solvent in the system. Thus claims 1-3, 6-13 and 15 are obvious over Friedl et al. in light of Gendron et al. and Parikh. Another embodiment of the invention taught by Friedl at el. employs the coating of carrier particles in a fluidized bed with the aqueous solution of telmisartan (see paragraph 38 lines 1-4). As Friedl et al. clearly envisioned the combination of the water soluble diluent with the alkaline solution of telmisartan and its solubility enhancer (see paragraphs 55, 49, 63 line 11, 84, 85 line 1, and 91-93), one of ordinary skill in the art at the time the invention was made would have found it obvious to use the water soluble diluent already specified by the formulation as the "carrier particles in a fluidized bed". The EPA Profile of the Pharmaceutical Manufacturing Industry teaches that ethanol is a common solvent used in the pharmaceutical industry, so it would have been

obvious to a person of ordinary skill in the art at the time the invention was made to employ ethanol as an additional solvent in the composition of Friedl et al. (see page 41 paragraph 2 line 13). In addition, Friedl et al. also teach the absence of the fluid from the telmisartan product (see example 4), implying the occurrence of a drying step. As the particles that result form the granulation that occurs in the spray coated fluidized bed may be larger than amenable to later tablet formation (see Parikh page 244), an artisan of ordinary skill would appreciate the need to employ some methodology (e.g. milling) to reduce the particle size. The resulting mixture can also contain other excipients and adjuvants (see paragraphs 51-58). Thus, claims 1-3 and 6-15 are obvious over Friedl et al. in light of Gendron et al., Parikh, and the EPA Profile of the Pharmaceutical Manufacturing Industry.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Caralynne Helm whose telephone number is 571-270-3506. The examiner can normally be reached on Monday through Thursday 8-4 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Caralynne Helm
Examiner
Art Unit 1609

CH

Ardin H. Marschel 9/14/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER